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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	660081.415C1	6324

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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07/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/648,816

Applicant(s)

YEAMAN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 67-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-69, 76 and 79 is/are rejected.
- 7) ☒ Claim(s) 70-75, 77 and 78 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of the Claims*

1. Claims 67-79 are pending.

Applicants' response filed on April 13, 2007 is acknowledged. Therefore, claims 67-79 are examined.

### *Maintained Claim Rejections-Obviousness Type Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 67-69, 76 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent 6,743,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69, 76 and 79 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acid core sequence that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3, 10 or 13. This is obvious variation in view of claim 1 of the patent which discloses an antimicrobial peptide comprising amino acid sequence of SEQ ID

NO:3, 10, 13 or 14. Both sets of claims cite an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13. Thus, claims 67-69, 76 and 79 in present application and claim 1 in the patent are obvious variations of an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13.

Response to Arguments

Applicants request that the rejection be held in abeyance until there is an indication of allowable subject matter at which time Applicants will file a Terminal Disclaimer if appropriate. (page 4 of the response). Since a terminal disclaimer is not filed, the rejection is maintained.

3. Claims 67-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U. S. Patent 7,067,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acid core sequence that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3. This is obvious variation in view of claims 1-8 of the patent which disclose a context-activating peptide comprising the amino acid sequence of SEQ ID NO:1, 2, 3 or 4, which contains the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys, and the specification indicates SEQ ID NO:1, 2, 3, or 4 has less anti-microbial activity than the anti-microbial peptide, RP-1 (column 4, line 50-column 5, line 56). Both sets of claims cite an antimicrobial peptide comprising the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys. Thus, claims 67-69 in present

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application and claims 1-8 in the patent are obvious variations of an antimicrobial peptide comprising the amino acid core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 67-68 are rejected under 35 U.S.C. 102(b) as anticipated by Darveau *et al.* (U. S. Patent 5,409,898, April 1995).

Darveau *et al.* disclose cationic oligopeptides include Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly and the like, wherein the amino acid residues can be d-amino acid (column 7, lines 46-49), which has  $\alpha$  helical amphiphilic structure and antibacterial activity (column 12, lines 31-32 and 49-54). The d-amino acid analog of the peptide has the sequence of dAla-dLeu-dTyr-dLys-dLys-dLeu-dLeu-dLys-dLys-dLeu-dLeu-dLys-dSer-dAla-dLys-dLys-dLeu-Gly (column 8, lines 15-17), which contains the synthetic analog of the 7 amino acid core sequence (Ala-Leu-Tyr-Lys-Lys-Phe-Lys) that retains antimicrobial activity (claims 67-68).

**Response to Arguments**

Applicants indicate the peptides set forth in the '898 patent differ from the claimed antimicrobial peptides by having non-identical natural amino acid residues at several positions. A synthetic analog of an amino acid is a non-natural amino acid (see Attachments A and B for the dictionary's definition of "analog"). A natural peptide having non-identical natural amino

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acids at several positions compared to the claimed antimicrobial peptides does not represent antimicrobial peptide of claims 67-68 (pages 4-5 of the response).

Applicants' response has been fully considered. Regarding the term "synthetic analogs", the arguments are persuasive. However, Darveau *et al.* also disclose a synthetic analog of the cationic oligopeptide of Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly, in which the amino acid residues are substituted with d-amino acids (column 7, lines 46-49; column 8, lines 15-17), which are the synthetic analogs of amino acids in the core sequence of the claimed peptide. Furthermore, the specification of the instant application (e.g., the second and third paragraphs at page 42) indicates synthetic analogs may include amino acid residues substituted with d-amino acid residues. Therefore, Darveau *et al.* anticipates the claimed peptide.

#### ***Claim Objections***

5. Claims 70-75, 77 and 78 are objected to because the claims are dependent from a rejected claim.

#### ***Conclusion***

6. Claims 67-69, 76 and 79 are rejected; and claims 70-75, 77 and 78 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

June 29, 2007